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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

RAO, MANJUNATH N

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 01/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/839,136

Applicant(s)

TANIGUCHI ET AL.

Examiner

Manjunath N. Rao, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 27-37 is/are pending in the application.
- 4a) Of the above claim(s) 30-34, 36 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-29 and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 08/913,805.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1 6) ☐ Other:

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### **DETAILED ACTION**

Claims 27-37 are still at issue and are present for examination. Claims 27-29 and 35 are now under consideration. Claims 30-34, 36-37 are withdrawn from consideration as being drawn to non-elected invention.

#### ***Election/Restrictions***

Applicant's election of Group I, claims 27-29 and 35 in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

#### ***Priority***

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 08/913,805, filed on 1-7-1998.

#### ***Drawings***

Drawings submitted in this application are accepted by the Examiner for examination purposes only.

***Claim Objections***

Claim 35 is objected to because of the following informalities: Claim 35 improperly depends from a non-elected claim. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27-28 are rejected under 35 U.S.C. 102(a) as being anticipated by Uozumi et al. (Biochemistry, 1995, Vol. 67(7):abstr. no.4053, recited in the IDS). This rejection is based upon the public availability of a printed publication. Claims 27-28 of the instant application are drawn to an isolated porcine  $\alpha$  1,6-fucosyltransferase capable of transferring fucose from GDP-fucose to hydroxy group at position 6 of N-acetylglucosamine, has an optimum pH of about pH 7.0, can retain activity after 5 hours of treatment at 4° C a pH range of 4.0-10.0, has an optimum temperature of about 30-37° C and has no requirement for divalent metal ions and is not inhibited in the presence of 5 mM EDTA and has a molecular weight of about 60,000 and is purified from porcine brain. Uozumi et al. disclose an identical  $\alpha$  1,6-fucosyltransferase isolated from pig brain. Therefore, Uozumi et al. anticipate claims 27-28 of this application as written.

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Claim 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Longmore et al. (Carbohydrate Res., 1982, Vol. 100 :365-392). This rejection is based upon the public availability of a printed publication one year before the filing of this application in this country. Claims 27 of the instant application are drawn to an isolated porcine  $\alpha$  1,6-fucosyltransferase capable of transferring fucose from GDP-fucose to hydroxy group at position 6 of N-acetylglucosamine, has an optimum pH of about pH 7.0, can retain activity after 5 hours of treatment at 4° C a pH range of 4.0-10.0, has an optimum temperature of about 30-37° C and has no requirement for divalent metal ions and is not inhibited in the presence of 5 mM EDTA and has a molecular weight of about 60,000. Longmore et al. disclose an identical  $\alpha$  1,6-fucosyltransferase activity isolated from pig liver. While the reference does not disclose the other characteristics of the enzyme, because the enzyme is from the same source, Examiner takes the position that all such characteristics would be inherent to the enzyme in the reference. Therefore, Longmore et al. anticipate claim 27 of this application as written. Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Longmore et al. as applied to claims 27 above, and further in view of the common knowledge in the art of molecular biology (provided by several Molecular biology laboratory manuals). Claims 28 is drawn to a  $\alpha$  1,6-fucosyltransferase purified from a porcine brain. The reference of Longmore et al. which discloses the isolation, of porcine-liver  $\alpha$  1,6-fucosyltransferase has already been discussed above. Using the isolation method of Longmore et al. it would have been obvious to one of ordinary skill in the art to isolate and purify the same enzyme from different organs of pig including the brain. It is common knowledge in the art that some enzymes are expressed more or less in certain tissues/organs depending on the function of the organ/tissue. One of ordinary skill in the art would have been motivated to isolate and purify the enzyme from brain for studying the molecular structure of the enzyme or simply to do a comparative study of the enzyme kinetics. One of ordinary skill in the art would have a reasonable expectation of success since Longmore et al. provide the isolated protein and the art provides several other techniques for isolating proteins in general from brain tissue.

Therefore, the above invention would have been *prima facie* obvious to one of ordinary skill in the art.

Claims 29 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uozumi et al. or Longmore et al. as applied to claims 27-28 above, and further in view of the common knowledge in the art of molecular biology (provided by several Molecular biology laboratory

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manuals). Claims 29 and 35 are drawn to a recombinantly produced porcine  $\alpha$  1,6-fucosyltransferase. The reference of Uozumi et al. which discloses the isolation, purification and characterization of porcine  $\alpha$  1,6-fucosyltransferase has already been discussed above. Using the purified enzyme taught by Uozumi et al. it would have been obvious to one of ordinary skill in the art to make the recombinant form of the same using the common knowledge of cloning available in the art of molecular biology. It is common knowledge in the art that recombinant proteins of a purified protein can be made by obtaining the amino acid sequence of a small portion of the purified protein followed by making oligonucleotide probes and synthesizing cDNA clones using a cDNA library. Once a full length cDNA clone becomes available, it is be subcloned into expression vector followed by transforming a host cell. Culturing such transformed host cells under conditions of ideal for expression of the heterologous polypeptide yields recombinant form of the purified protein. Several commercial kits are available in the art to perform such experiments including several commercial cDNA libraries of several model animals including porcine brain cDNA library. One of ordinary skill in the art would have been motivated to make a recombinant form of the above protein for either making the protein in larger amounts, or for studying the molecular structure of the enzyme or simply to study the enzyme kinetics in more detail. One of ordinary skill in the art would have a reasonable expectation of success since Uozumi et al. provide the purified protein and the art provides the techniques for making a recombinant form of the above protein.

Therefore, the above invention would have been *prima facie* obvious to one of ordinary skill in the art.

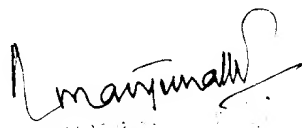
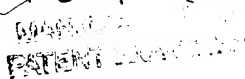
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*Conclusion*

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.

Manjunath N. Rao  
January 6, 2003